

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

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of

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**Complete if Known**

Application Number	09/787,461
Filing Date	March 2, 2001
First Named Inventor	Esteban Cvitkovich
Art Unit	1614
Examiner Name	Phyllis Spivack
Attorney Docket Number	13566.105002

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Alexopoulos, "Phase II study of pegylated liposomal doxorubicin (Caelyx(R)) and docetaxel as first-line treatment in metastatic breast cancer," Ann. Oncol., 2004, 15(6):891-5	
		D'Incalci et al., "Unique Features of the Mode of Action of ET-743," The Oncologist, 7, p. 210-216, June 2002	
		Goodman & Gilman's The Pharmaceutical Basis of Therapeutics, page 36, 1975	
		Gourley C. et al., "Malignant mixed Mesodermal Tumours - Biology and Clinical Aspects," European Journal of Cancer 2002, vol. 38, no. 11, pages 1437-1446	
		Halm et al., "A phase II study of pegylated liposomal doxorubicin for treatment of advanced hepatocellular carcinoma," Ann. Oncol., 2000, 11(1):113-114	
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		Horstmann et al., "Risks and Benefits of Phase I Oncology Trials, 1991 through 2002," New England Journal of Medicine, vol. 352, pages 895-904; March 3, 2005	
		Puchalski et al., "Pharmacokinetics of Ecteinascidin 743 Administered as a 24-h Continuous Intravenous Infusion to Adult Patients with Soft Tissue Sarcomas associations with Clinical Characteristics, Pathophysiological Variables and Toxicity," Cancer Chemotherapy and Pharmacology, 2002, vol. 50, no. 4, pages 309-319	
		Rote Liste 2002 "Doxorubicin," entries 86-056 through 86-062, 2002	
		Schwartzmann G. et al., "Marine Organisms as a Source of New Anticancer Agents," The Lancet Oncology, 2001, vol. 2, no. 4, pages 221-225	
		Twelves et al., "Phase I and pharmacokinetic study of Yondelis™ (Ecteinascidin-743; ET-743) administered as an infusion over 1 h or 3 h every 21 days in patients with solid tumours," European Journal of Cancer, vol. 39, p. 1842-1851, 2003; available online August 14, 2003	
		Wollina, "Multicenter study of pegylated liposomal doxorubicin in patients with cutaneous T-cell lymphoma," Cancer 2003, 1:98(5):993-1001, published online July 24, 2003	
		Wright et al., "Antitumor Tetrahydroisoquinoline Alkaloids from the Colonial Ascidian Ecteinascidia Turbinata", J. Org. Chem., vol. 55, pp. 4508-4512, 1990	

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SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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